

01/08/2016 reference H3686

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To whom it may concern,

Citriclce

- Product description: cleaner (low pH detergent)
- Product use: vehicle washing (dairy farm transportation tankers, external cleaning and rendering, non-food contact for dairy industry equipment).

"Passed AsureQuality assessment for food/beverage/dairy factory vehicle cleaner for no contact with food contact surfaces" with conditions. This assessment was prepared by Global Proficiency Ltd using HACCP principles to determine equivalence with food standards listed below. See <http://assessedproducts.asurequality.com/> This supports food Risk Management Programmes & other endorsements that may apply to this product include MPI regulated farm dairy approval, MPI dairy factory endorsement, MPI regulated non-dairy animal product approvals, EPA HSNO-OSH-environment approval (& previously AQIS).

Conditions:

- Used according to Manufacturer's Instructions, Good Manufacturing Practice (GMP), and applicable legislation as vehicle/ truck external wash with no contact with food/milk contact surfaces.
- Usage and carry-over to food should be avoided to ensure food function or composition are not affected, that residues are within applicable Maximum Residue Limits (MRLs/MAVs), and that food legislation requirements are met
- The assessment is subject to notification of change (e.g. in formulation, raw materials or instructions) and expires on 01/08/2021).
- The full report is attached for supplier review and verification. The assessment is activated by countersigning.

Prepared by Global Proficiency for AsureQuality Ltd...



Supplier:.....

Date:.....

Scope and purpose of the assessment:

- Asurequality assessment is a non-regulated, voluntary, and evidential certification by the supplier demonstrating equivalence with food safety standards, and also that product instructions address hazards for staff & equipment. The assessment is independently confirmed, without prejudice or guarantee, using information submitted by the supplier or from other sources. Confidentiality of the product formulation is maintained using coded material identifiers in the report, and appendices containing confidential information are provided only to the supplier.
- Scope: NZ checks (FSANZ, US FDA 21 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings or related data for equivalent safety). NZ background (Animal Products Act, Risk Management Programmes. Detergent & Sanitiser Manufacturer's Code of Practice, Detergent & Sanitiser Standards and Analytical Methods. Quality Manual - Assessment Procedures

Summary of assessment with risks highlighted:

- Status of information/ prior assessment (New AsureQuality assessment. for food/ beverage/ dairy factory).
- Food safety (per raw material food/ safety listings, w/o purities & no contact).
- QA (Cleaning Systems design & manufacture of cleaning systems. ISO 9001:2008, operations ISO 14001:2004).
- QC (Chemistry Sighted ID of raw material. Typical properties of the product were listed & Micro safety is per low pH outside pathogen growth ranges).
- Instructions
 - Label (Citriclce a low pH detergent use in 2-step acid/ alkali pre-soak for touchless use including truck washes, trains & railcars, hybrid & friction systems & bumper prep application. Used with high pH re-soak (Intergreen, Britec, TransClean, provides easier rinsing and removal of Calcium spots from vehicles. Colour Orange, scent mild citrus, foam moderate-high. Guidelines 1:60 parts water & accepts hard water at increased strength 10% per grain of hardness. Use temperature summer 70-90F, winter 90-100F. Use 15-25 seconds between application & high pressure rinse & decrease dwell if hot. Use Frictionless & hybrid/friction 1:60-1:100. Bumper prep 1:10 - 1:30).
 - MSDS (Manufacturer CIS and NZ supplier is Tranzwash etc. NZ Poisons Centre phone no. Hazards Danger 1B Corrosive. H314 Causes severe skin burns and eye damage. Pictogram. Precautions list. Composition Ingredients Phosphoric acid CAS 7664-38-2 10-20%. Proprietary surfactant blend 5-10% acute toxicity oral 4, eye dam irreversible 1. 2-Butoxyethanol CAS 111-76-2 1-5%, d-limonene CSA 5989-27-5 flammable liquid 3, skin irritant 2, skin sensitivity 1, aquatic toxicity 1, aquatic chronic 1. S. Panels for first aid etc. Exposure controls. Properties pH 1/1% (outside pathogen growth ranges). Regulatory says EPA SARA Title III section 312 (40 CFR 370) Hazard classification of ingredients - acute health hazard. "This product does not contain chemical(s) known to state of California to cause cancer, birth defects or other reproductive harm All materials on TSCA directory").
- Adverse effects (per label & MSDS & per USA - HSNO & EPA NZ registration not sighted. Production side effects appear ok per the food listings and purity & common listed uses & no contact with food contact surfaces - with some care).
- Efficacy & related data: (This is inferred only from the formula & prior USA use)

Contents (This is a simplified report with sections 2-11 replaced by a summary on p1 and in the table in section 1)

0 Information is to be evidential (std 0).	1 Materials safety and residues etc
2 Material (other – function)	3 Quality assurance certificate
4 Purity (or Design, formulation, fabrication and finish).	5 Instructions
6 Freedom from apparent side effects	7 Efficacy or hygiene to meet food safety margins
8 Packaging safety.	9 Summary of submitted information etc
10 Standards/References - front page/may be attached	11 Contacts.
12 Confidential information re design, formulation etc.	13 Covering letter & then 14 Raw material confidential information

Risk-Rating (failure/accident)

	Chemical	Microbiological
Incidence	Low	Low
Susceptibility	Low	Low
Severity	Low	Low
Total	Low	Low

Evaluation: Note that Standards vs. submission-responses yield compliance status in each of the sections below.

Nature of information

0 Standard: Assurance information is to be evidential/cross-registered/or ex accredited bodies (and approvals may need levels of independence for toxicity and efficacy).

- Status of information/ prior assessment (New AsureQuality assessment. for food/ beverage/ dairy factory).

Raw materials:

1 Standard:

Raw materials are to be identified safe: traceably identified, non-toxic, and pure - depending on the level of contact. Raw materials are to be safe at residue levels with safety factors (simplified here eg per cross-registration of USFDA 21 CFR/ ANZF/ EU etc registrations factored for likely equivalence and recognising high 1.5 L milk consumption would have been required by FDA etc – refers to supplier confidential appendix but with identifiers excluded

Response

(Tranzwash NZ Ltd) (Cleaning Systems Incorporated 1997) Citriclce H3686. 01-08-2016. Formula confidential to CSI	Registrations column. Scope: NZ checks (NICNAS AICS. FSANZ, US FDA 21 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings or related data for equivalent safety). NZ background (Animal Products Act, Risk Management Programmes. Detergent & Sanitiser Manufacturer's Code of Practice, Detergent & Sanitiser Standards and Analytical Methods. Quality Manual - Assessment Procedures	Purity column Scope: Purity column raw purities to be per FSANZ purity wanted (as ingredient etc.) FCC7 2010-2011 with GMP indicators & FSANZ also (require Pb<2, As<1, Heavy metals <40 mg/kg). Purity column.
HACCP analysis of instructions and the calculation overestimates residue carryover as it is based on the farm model)	Instructions label (Citriclce a low pH detergent use in 2-step acid/ alkali pre-soak for touchless use including truck washes, trains & railcars, hybrid & friction systems & bumper prep application. Used with high pH re-soak (Intergreen, Britec, TransClean, provides easier rinsing and removal of Calcium spots from vehicles. Colour Orange, scent mild citrus, foam moderate-high. Guidelines 1:60 parts water & accepts hard water at increased strength 10% per grain of hardness. Use temperature summer 70-90F, winter 90-100F. Use 15-25 seconds between application & high pressure rinse & decrease dwell if hot. Use Frictionless & hybrid/friction 1:60-1:100. Bumper prep 1:10 - 1:30).	MSDS (Manufacturer CIS and NZ supplier is Tranzwash etc. NZ Poisons Centre phone no. Hazards Danger 1B Corrosive. H314 Causes severe skin burns and eye damage. Pictogram. Precautions list. Composition Ingredients Phosphoric acid CAS 7664-38-2 10-20%. Proprietary surfactant blend 5-10% acute toxicity oral 4, eye dam irreversible 1. 2-Butoxyethanol CAS 111-76-2 1-5%, d-limonene CSA 5989-27-5 flammable liquid 3, skin irritant 2, skin sensitivity 1, aquatic toxicity 1, aquatic chronic 1. S. Panels for first aid etc. Exposure controls. Properties pH 1/1% (outside pathogen growth ranges). Regulatory says EPA SARA Title III section 312 (40 CFR 370) Hazard classification of ingredients - acute health hazard. "This product does not contain chemical(s) known to state of California to cause cancer, birth defects or other reproductive harm All materials on TSCA directory").
HACCP analysis of features other than instructions	Status of information/ prior assessment (New AsureQuality assessment. for food/ beverage/ dairy factory). Food safety (per raw material food/ safety listings, w/o purities & no contact). QA, (Cleaning Systems design & manufacture of cleaning systems. ISO 9001:2008, operations ISO 14001:2004). QC (Chemistry Sighted ID of raw material. Typical properties of the product were listed & Micro safety is per low pH outside pathogen growth ranges)	Adverse effects (per label & MSDS & per USA - HSN0 & EPA NZ registration not sighted. Production side effects appear ok per the food listings and purity & common listed uses & no contact with food contact surfaces - with some care). Efficacy & related data: (This is inferred only from the formula & prior USA use)
Raw 1 ubiquitous	Ubiquitous & safe	N/a
Raw 2 Surfactant	NICNAS AICS (listed not requiring secondary notification).EPA NZ (list shows HSR00xxxx without restriction, CCID shows acutely toxic, skin irritant corrosive to eyes, eco-toxic to aquatics & soil and harmful to vertebrates). FSANZ Food Standards Code (1.3.3.12 Permitted washing and peeling with GMP) USA FDA 21CFR Non-toxicity: registered for use as a food contact surface sanitiser regulated per USA FDA 21 CFR	Purity wanted per column header) Purity found (not found or required for nil-incident contact here).

	178.1010 not in excess, drained, not necessarily rinsed, not extended to dairy, limited in USA to <400 ppm acid, 25-430 ppm sodium salt, un-rinsed application. This material is a moderate eye irritant and may cause skin inflammation, rashes or dermatitis with prolonged and repeated contact. Oral Mus LD50: >2000 mg/kg. TLV: 5 mg/m3. Non-carcinogenic. The ingredients of this material are subject to label identification according to the New Jersey Right-to-Know list.	
Raw 3 Acid	NICNAS AICS found recorded as not assessed. FSANZ FS Code (1.3.3.3 processing aids GP with GMP. & 1.3.1 schedule 1 cheese & kolas found, schedule 2 unfound). USA FDA (21 CFR 182.1073 GRAS with GMP, USDA 9 CFR 318.7, 381.147 sufficient for purpose and limitation of 0.01% in lard shortening and poultry fat). Lewis toxicity data (Community-Right-To-Know List. EPA genetic toxicology program. OSHA-PEL; TWA 1 mg/m3, STEL 3 mg/m3, ACGIH TLV: TWA 1 mg/m3, STEL 3 mg/m3. Human poison by unspecified route, moderately toxic by ingestion and skin contact. Corrosive agent to eyes, skin and mucous membranes, and a systemic poison by inhalation. A strong acid with neutralisation into food).LDL man 220 mg/kg, skin rabbit 595 mg/24hr severe, eye rabbit 119 mg severe.	EPA NZ (>10% Classification 6.1D (oral) Acutely toxic 6.1E (dermal) Acutely toxic 8.1A Corrosive to metals 8.2C Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1D (other) Slightly harmful in the aquatic environment or are otherwise designed for biocidal action 9.3C Harmful to terrestrial vertebrates). Side effects (ERMA and IDF Bull 288 not negatively listed). Efficacy: is per positive listing in IDF 9101, BS 5305. Purity wanted (per column header & US FCC 7 (10-11) Pb 10, Hg 1 mg/kg & FSANZ also require Pb<2, As<1, Heavy metals <40 mg/kg). Purity found (not found or required for nil-incident contact here).
Raw 4 Acid	USA FDA 21 CFR 182.1033, 182.6033, GRAS with GMP, USDA 9CFR 318.7. Acidifier, flavouring agent....for beef (cured), fats (poultry), fruits (frozen)....Poison by intravenous route, moderately toxic by subcutaneous and intra-peritoneal routes, mildly toxic by ingestion. Severe eye and moderate skin irritant. Toxicity data -skin-rabbit 500mg/24H MOD, eye-rabbit: 750ug/24H SEV, oral-rat: LD50: 6730mg/kg: intra-peritoneal-rat LD50:883mg/kg. ANZFA '2000 1.3.1. Food additives schedule 2 FOUND for addition to those process/foods w/o exclusions. Acidity regulator found, preparations of food additives - no, baking compounds - no, flavourings - no, rennet enzymes no, liquid milk products no except UHT goats milk, fermented and renneted milk products, condensed & evaporated milk no exclusions,	For cream reduced cream and light cream except UHT had no exclusions, cream products-no, dried milks-no(?), cheese/products-no (?), edible oils.. no, ices/creams no, fruits - no, confectionery no, cereals and breads no, meats no, fish no, eggs no, HSNO & environment are in EMANZ scope Approval Number HSR006695 Classification 6.4A Irritating to the eye and with other side effects also per these food listings and IDF Bull 288 & process side effects and efficacy per IDF 9101, BS5305 etc. Purity wanted (see the column header). Purity found (not found or required per low risk here).
Raw 5 Solvent	Intermediate Volatility BP 171-2C. NICNAS AICS listed as not assessed. EPA NZ HSR00xxxx w/o exclusions. FDA 21CFR 178.1010 listed as food contact surface sanitiser ingredient. FSANZ FS Code 1.3.3.3 similar. . May be reviewed per ready alkyl C2 degradation path.	Purity wanted (per column header) Purity found (not found or required for nil-incident contact here).
Raw 6 Wetting agent	NICNAS AICS listed w/o concern. EPA NZ listed HSR00xxxx. USAFDA21CFR178.1010 - FOUND - similar to alpha lauryl-omega-hydroxy-polyoxyethylene with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. Per 21CFR178.1010 - for food and milk containers but not as a final rinse. Also similar to alpha alkyl - omega hydroxy-poly(oxyethylene) by condensation of C11-13 straight chain randomly substituted secondary alcohols with an average of 7-20 moles of ethylene oxide. For emulsifiers and or surface active agents for articles for food manufacture. Also compare 21 CFR173.315.	FSANZ Food Standards Code 1.3.3.3 processing aids generally - FOUND.P Side effects are ok per BS5750 and IDF Bull 288 environmental listings. Efficacy is per BS 5750 and IDF 9101, & 9701 listings. Purity wanted (per column header) Purity found (not found or required for nil-incident contact here). .
Raw 7 Wetting agent	NICNAS AICS listed w/o concern. EPA NZ listed HSR00xxxx. USAFDA21CFR178.1010 - FOUND - similar to alpha lauryl-omega-hydroxypolyoxyethylene with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. Per 21CFR178.1010 - for food and milk containers but not as a final rinse. Also similar to alpha alkyl - omega hydroxypoly(oxyethylene) by condensation of C11-13 straight chain randomly substituted secondary alcohols with an average of 7-20 moles of ethylene oxide. For emulsifiers and or surface active agents for articles for food manufacture. Also compare 21 CFR173.315.	FSANZ Food Standards Code 1.3.3.3 processing aids generally - FOUND.P Side effects are ok per BS5750 and IDF Bull 288 environmental listings. Efficacy is per BS 5750 and IDF 9101, & 9701 listings. Purity wanted (per column header) Purity found (not found or required for nil-incident contact here). .
Raw 8 Surfactant	Bridged by similar entries in USAFDA21CFR178.1010 food contact surface sanitisers and .3570 emulsifiers. ANZFA 1.3.3.3 GP process aids used with GMP has entries for the backbone/metabolite. Side effects and efficacy are per these food listings & possibly side effects coverage in IDF Bull 288.	Purity wanted (per column header) Purity found (not found or required for nil-incident contact here).
Raw 9 Solvent	Food listing/non-toxicity: food listed 21CFR182.60 direct flavouring substance and FSANZ allows permitted synthetic flavourings. Safety Limonene and its oxidation products are skin and respiratory irritants, and limonene-1, 2-oxide (formed by aerial oxidation) is a known skin sensitizer. Most reported cases of irritation have involved	Purity wanted (per column header) Purity found (not found or required for nil-incident contact here).

	long-term industrial exposure to the pure compound, e.g., during degreasing or the preparation of paints. However, a study of patients presenting dermatitis showed that 3% were sensitized to limonene. Although high doses have been shown to cause renal cancer in male rats,[21] limonene is considered by some researchers to be a potential chemo-preventive agent [22] with value as a dietary anti-cancer tool in humans.[23] There is no evidence for carcinogenicity or genotoxicity in humans. The IARC classifies d-limonene as a Group 3 carcinogen: not classifiable as to its carcinogenicity to humans.[20][24]	
Raw 10 inhibitor	Toxicity (including Thor data): US 21 CFR Chapter 1 accepted at a ratio of 3:1 in calcium chloride at a ratio of 2.5lb/ton of dry fibre when used as a slimicide for paper and cardboard (1000ppm with limited transfer to the contents likely to exceed the residue calculation for an extreme accident with 1 & 2HE separation and providing a further safety margins for "no possible contact"). There is an apparent large safety margin relative to paper and paperboard use (and likely relative to the submitted chronic and sub-chronic toxicity data - contents 4). Apparently food safe in this application (but use care in handling - TWA 0.1mg/cubic meter. Can be a hazardous material see formulation data above). Toxicity - 2nd supplier. Accidental consumption: The NOEL is 225 ppm or 20 mg/kg/day for active ingredient for rat drinking water trials with (only) 1 generation reproduction. .At accidental leakage detected around 1% food may need to be rejected for this or microbiological reasons). Toxicity 3rd supplier. Further Toxicological information. LD50 oral rat 457 mg/kg, Teratology rabbit negative, Reproductive toxicity rat negative, Pharmacokinetics rat 2.5 mg/kg/day & 90% excreted in 3 days, Dermal LD50 rabbit note DOTM181 packing group III: corrosive to skin in 240 minutes but not 60 minutes,	Inhalation LC50 rat 2.6 mg/L/4hr, Skin irritation rabbit 8/1 hour exposure (2.3/48 hr, 0.8/36 hr), Eye irritation score rabbit corrosive, 90 Day feed study rat >30 mg/kg/day, Skin sensitisation Guinea pig positive and negative, Ames assay equivocal - note most strains gave negative response, Non-Ames mutagenicity various most negative (note unscheduled DNA: negative; Mouse lymphoma: positive; In vivo and in vitro Cytogen: neg. Purity is uncritical as at no/low concentration & contact HSR002759 Classification 6.1B (oral) Acutely toxic 6.1B (dermal) Acutely toxic 6.1B (inhalation) Acutely toxic 6.5B (contact) Contact sensitisers 8.2B Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1A (fish) Very eco-toxic in the aquatic environment 9.1A (crustacean) Very eco-toxic in the aquatic environment 9.1A (algal) Very eco-toxic in the aquatic environment 9.3A Very eco-toxic to terrestrial vertebrates. MICs gram positives (7) 150-600 active 2-9 mg/kg, gram negatives 50-600 active 0.75-9 mg/kg, fungi (14) 150-600 active 2-9 mg/kg.
pH vs HD/GP margins of pH 2 & 12.5s. IDF 9101 guide alkalinity 0.02-0.5%, sequestrant 0.005-0.5%, surfactant 0-0.05%.	pH growth ranges: B cereus 4.4-9.3, Campylobacter jejuni 4.9-9.0, C botulinum A & B 4.8-8.5 type E 5-8.5, C perfringens 5-8.9, Listeria monocytogenes 4.5-8.0, Salmonella 3.8-9,	Staph aureus 4.3-9.0, vibrio cholerae 6-11, vibrio parahaemolyticus 4.8-9, vibrio vulnificus 5-10, Yersinia enterocolitica 4.4-9.6

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- Food safety (per raw material food/ safety listings, w/o purities & no contact).

12 The formulation in confidence follows & is not for public circulation